

REMARKS

Claims 1-12 are pending in the application. Claim 9 is amended. Support for the amendment can be found in paragraph [0005] of the U.S. published application no. 20070065493, which is the publication of the present application.

Claim Rejections – 35 USC § 103

Claims 1-3, 5-7, and 9-11 were rejected as being unpatentable over Hirano et al. (JP 11-001441) of record, in view of Blank et al. (US Patent 5,128,138). Hirano describes a percutaneously absorbable preparation containing

- a. 10-30% of a styrene-isoprene-styrene block polymer ["I"];
- b. 10-60% of a softening agent ["S"];
- c. 20-60% of a tackifying resin ["R"]; and
- d. 1-10% of hexylene glycol ["A"], all based on weight.

Meanwhile, Blank describes a mixture of estrogen with an uncross-linked, water-insoluble vinylpyrrolidone copolymer. The water-insoluble vinylpyrrolidone copolymer is produced by the copolymerization of vinylpyrrolidone ["V"] with one or more appropriate comonomer ["C"] (see column 4, lines 54-59). According to this rejections, a person having ordinary skill of the art would combine I + S + R + A with V + C, then drop A and C to arrive at I + S + R + V.

First of all, there is no reason or suggestion why one would break up the uncrosslinked, water-insoluble vinylpyrrolidone copolymer of Blank and use only the vinylpyrrolidone portion in a polyvinylpyrrolidone form. Secondly, there is nothing in either reference that would suggest the elimination of hexylene glycol. Hexylene glycol is a key element of the Hirano reference (see paragraphs [0013] and [0014] of Hirano). Why would a person having ordinary skill in the art would eliminate this water-soluble key element and add instead the vinylpyrrolidone portion of the water-insoluble vinylpyrrolidone copolymer of Blank? The preparation disclosed in the Hirano reference would not even be an attractive starting material for experimentation, since hexylene glycol is a diol and like another alcohol, ethanol, is an irritant (see exhibit A and

paragraph [0005] of the application). One of the advantages of the preparation of the present application is reduced skin irritation as shown in Table 4 (see paragraphs [0044] and [0045] of published application).

As stated in the recent Board of Patent Appeals and Interference's decision, Ex parte Francis X. Hursey, Appeal 2009-003346, Decided June 11, 2009, <http://dea.uspto.gov/Foia/RetrievePdf?system=BPAI&fNm=fd2009003346-06-11-2009-1>, page 4:

... obviousness requires a suggestion of all the elements in a claim (*CFMT, Inc. v. Yieldup Int'l Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003)) and "a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007).

There is no suggestion of all the elements in the claims of the present invention, as amended and currently pending, in the prior art references and no reason why a person of ordinary skill would combine these elements "in the way the claimed new invention does." Both references teach estrogen delivery systems. There is no reason to rearrange and combine elements to achieve the present invention. Applicants respectfully maintain that the claims as filed and amended are in condition for allowance.

Claims 4, 8 and 12 were also rejected as being unpatentable over Hirano et al. (JP 11-001441) of record, in view of Blank et al. (US Patent 5,128,138) and further in view of Azuma et al. (US Patent 5,200,190). The same arguments apply to this rejection as discussed above. Since the adhesive layer of the present application is unobvious over the teaching Hirano in view of Blank, applicants respectfully submit that the addition element of the backing is not relevant.

CONCLUSION

If the Examiner has any questions or suggested Examiner's amendments, the Examiner is respectfully requested to call the undersigned.

The Commissioner is hereby authorized to charge any additional fees, or to credit any overpayment, to Deposit Account No. 50-3195.

Respectfully submitted,

Date: November 10, 2009

/Manette Dennis/
Manette Dennis (Reg. No. 30,623)
Ostrager Chong Flaherty & Broitman, P.C.
570 Lexington Avenue, Floor 17
New York, NY 10022-6894
Tel.: 212 681-0600
Fax: 212 681-0300
mdennis@ocfblaw.com

Appendix

1. Exhibit A -- Hexylene glycol